

## REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 7 and 19 are being cancelled.

Claims 1, 2-4, 8-10, 12-16, 20-27, 30, 34-35, and 38 are currently being amended. Support for the claim amendments is found, at least, in the claims as originally filed, e.g., claim 7, the specification, e.g., page 2, lines 24-25, page 2, line 27 to page 3, line 2, page 7, lines 11-28, and the figures, e.g., figures 2C, 6A, and 6B. No new matter has been added.

Claims 49-51 are being added. Support for the claim amendments is found, at least, in the claims as originally filed, e.g., claims 9-10, the specification, e.g., page 7, lines 19-28, and the figures, e.g., figures 2C, 3B, 6A, and 6B. No new matter has been added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-6, 8-18, 20-30, and 32-51 are now pending in this application, of which claims 39-48 were previously withdrawn.

## Examiner Interview

Applicant thank Examiner Sorkin for a helpful interview on October 20, 2008. In that interview, the following issues were addressed by the Applicant and the Examiner: (i) the claim rejections in view of Jorgensen et al. (US 2002/0107131); (ii) the claim rejections in view of Drucker (U.S. 3,675,846); and (iii) the claim rejections in view of Mercier (U.S. 4,610,369). Also, the Examiner provided suggestions regarding claim amendments in view of the cited

references. The Applicant has substantially utilized the Examiner's suggestions regarding claim amendments in the amended claims. As such, Applicants submit that Claims 1-6, 8-18, 20-30, 32-38, and 49-51, as now amended, are allowable.

### **Rejections Under 35 U.S.C. 112**

*Claims 1-30 and 32-38 are rejected under 35 U.S.C. 112 first paragraph, as failing to comply with the written description requirement.*

Applicant respectfully disagrees with the rejection of claims 1-30 and 32-38 under 35 U.S.C. 112 first paragraph as failing to comply with the written description requirement. However, to expedite prosecution, the Applicant has amended the claims to remove the term "reinforced." As such, since the claims, as now amended, do not include the term "reinforced," then the 112 first paragraph rejection should, respectfully, be withdrawn.

### **Rejections under 35 U.S.C. 102 and 103**

**Drucker --** *Claims 1-6, 11, 13-18, 24-29 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Drucker (US 3,675,846).*

Drucker describes a continuous-flow centrifuge head that includes a plastic bag that rotates with the chamber and serves as a liner for the chamber. (Drucker: col. 2, lines 56-57). In particular, "the plastic bag is suspended around the neck 55a on the central bracket." (Drucker: id.). As further described by Drucker, the bag may be supported by cords around its neck and around the neck 55a of the bracket, or by an O-ring in the upper annular groove 55b. (Drucker: col. 2, lines 52-60). Thus, the only open end of the plastic bag is positioned against the neck 55a of the central bracket and held into place using cords. As illustrated in FIG. 3 of Drucker, the

plastic bag may follow the interior contour of the chamber with a single open end of the plastic bag.

The present application, as described in the independent claims 1, 13, 24, and 34, as now amended, utilizes a bag with two sides, the first side and the second side, and each side has “a respective central opening for housing a central hub.” In contrast, Drucker describes the bag as including a single open end for attachment to the central bracket. Drucker does not describe or suggest a bag with two openings for connection to a central hub. As such, in operation, the bag as described in Drucker could not be connected to a central hub that connects a plurality of bags as illustrated in Figure 1 of the present application, since the bag as described in Drucker only has a single opening. Rather, the bag as described in Drucker is used in a single bag operation of the continuous-flow centrifuge head as illustrated in Figure 3 of Drucker. Thus, Drucker does not describe a bag with two sides, the first side and the second side, each side having “a respective central opening for housing a central hub.”

Accordingly, Drucker does not describe the elements of independent claims 1, 13, 24, and 34. As such, independent claims 1, 13, 24, and 34 and claims 2-6, 11, 14-18, 25-29, and 49-51, which depend from claims 1, 13, and 24, respectively, are now in a condition for allowance based on their distinctions from the cited reference.

**Mercier** -- *Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Mercier (US 4,610,369).*

Mercier describes a pressure vessel including a rigid container having a deformable partition therein and a plurality of closure elements normally extending radially outward. (Mercier: Abstract, see also figures 3 and 5). The pressure vessel includes a pair of ports for charging and discharging the vessel with fluids. (Mercier: id.). Mercier describes a portion of a bladder 13 positioned adjacent to the central opening and the bladder 13 includes flanges 39, 40

that snugly encompass the outer surface of a guide tube 27. (Mercier: col. 4, lines. 12-13, see also figure 3). Mercier further describes using an O-ring 42 to force a portion of the flange material into an associate annular groove. (Mercier: col. 4, lines. 15-20). In particular, Mercier describes the “outer surfaces of flanges 39 and 40 [as having] an annular groove 41 in which an ‘O’ ring 42” is securely positioned to securely retain the associated flange in position. (Mercier: id.). The “O” ring forces a portion of the flange material into an associated annular groove 42’. (Mercier: id.).

The present application, as described in the independent claims 1 and 13, as now amended, utilizes a mating portion that “in cross-section, includes at least one of a raised or recessed shape with respect to the interior surface” and “the first mating portion opposing an interior surface of the second side.” Thus, as illustrated in Figures 2C and 6A, the raised or recessed shape, e.g., the raised portion 210, of the present application, in cross-section, is raised or recessed with respect to the interior surface of the second side of the bag. Furthermore, the first mating portion in the present application provides a mechanical mechanism for holding the bag onto the hub while the hub is rotating. In other words, the position of the first mating portion opposite an interior surface of the second side provides for a mechanical structure that is directed perpendicular to the gravitational forces applied, so as to provide a mechanical interference with a corresponding mating portion of the hub to hold the bag onto the hub reliably under centrifugal force. In contrast, Mercier relies on a separate “O” ring that forces the flanges 39, 40 into an associated annular groove 42’. In Mercier, as illustrated in Figure 5, the “O” ring 42 is applying a mechanical force that is parallel to any gravitational forces that would be applied if the guide tube was rotating. Notwithstanding any rotation, neither the “O” ring as described in Mercier, nor the indentations in either flange caused therefrom is opposite an interior surface of a second side. Rather, the “O” ring as described in Mercier is simply placed further down the guide tube, i.e., not opposite the interior surface of the second side, as illustrated in Figures 4 and 5.

Accordingly, Mercier does not describe the elements of independent claims 1 and 13. As such, independent claims 1 and 13 and claims 2-6, 8-12, 14-18, 20-23, and 49-51, which depend

from claims 1 and 13, respectively, are now in a condition for allowance based on their distinctions from the cited reference.

**Jorgensen** -- *Claims 1-19 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Jorgensen et al. (US 2002/0107131). Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. (US 2002/0107131).*

Jorgensen describes centrifuge processing bags that include “an outer expressor bag 96, an inner processing bag 98, outer weld rings 100, inner weld rings 102 and hub 104.” (Jorgensen, paragraph 0050, see also Figures 7, 11, and 12). As illustrated in Figures 11 and 12 of Jorgensen, the assembled processing bag utilizes the weld rings 100 and 102 to secure the bags 96 and 98 to the hub 104. The bags 96 and 98 in Jorgensen do not include a first mating portion that includes “at least one or a raised or recessed shape with respect to the interior shape” or “the first mating portion opposing an interior surface of the second side” of the bag. Rather, Jorgensen describes locking the bags onto the hub utilizing the weld rings. (Jorgensen, paragraphs 0044, 0011, and 0013). As a result, the bags described in Jorgensen are susceptible to slippage at the joint between the bag and the hub in the presence of centrifugal forces. The centrifugal forces experienced by the fluid-filled bag pull the Jorgensen bags away from the hub. In contrast, the first mating portion in the present application includes “at least one of a raised or recessed shape with respect to the interior surface” and opposes “an interior surface of the second side.” Thus, the shape in the present application provides a mechanical mechanism for holding the bag onto the hub while the hub is rotating. In other words, the position of the first mating portion opposite an interior surface of the second side provides for a mechanical mechanism for preventing slippage of the bags away from the hub.

Accordingly, Jorgensen does not describe the elements of independent claims 1, 13, and 34. As such, independent claims 1, 13, and 34 and claims 2-6, 8-12, 14-18, and 49-51, which

depend from claims 1 and 13, respectively, are now in a condition for allowance based on their distinctions from the cited reference.

**Schultz** -- *Claims 30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. in view of Schultz (U.S. 3,982,691).*

Jorgensen is discussed above. As such, the remarks regarding Jorgensen are not repeated herein.

Schultz describes “a centrifuge device for separating and/or washing finely-divided solid particulate material suspended in a liquid.” (Schultz, Abstract). Schultz does not described a bag with two sides, the first side and the second side, and each side has “a respective central opening for housing a central hub.” In contrast, Schultz describes four assembly plates with pathways that are combined to provide for the separating and/or washing of the liquid. (Schultz, col. 7, lines 15-37, see also Figure 1). Furthermore, Schultz describes that the plurality of blood cell receiving means 10 as described therein provide better efficiency than bags since the receiving means 10 can be cleaned and reused. (Schultz, col. 9, lines 3-20). As such, Schultz does not describe a bag that includes a first and second side, and each side has a respective central opening for housing a central hub. Rather, Schultz describes not utilizing a bag for centrifuge device, but, as illustrated in Figure 1, describes a centrifuge device with multiple plates with various pathways for the fluid.

Accordingly, Schultz and Jorgensen do not describe the elements of independent claim 30. As such, independent claim 30 and claims 32 and 33, which depend from claim 30, are now in a condition for allowance based on their distinctions from the cited reference.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Oct. 22, 2008

By /s Christopher E. Everett/

FOLEY & LARDNER LLP  
Customer Number: 48329  
Telephone: (617) 342-4093  
Facsimile: (617) 342-4001

Ralph Tremontozzi  
Registration No. 55,686

Christopher E. Everett  
Registration No. 51,659

Attorneys for Applicants